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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/584,141	06/26/2006	Yoshihiro Takayanagi	292509US0PCT	5661

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1940 DUKE STREET
ALEXANDRIA, VA 22314

EXAMINER

HAVLIN, ROBERT H

ART UNIT	PAPER NUMBER
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1626

NOTIFICATION DATE	DELIVERY MODE
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09/04/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/584,141	Applicant(s) TAKAYANAGI ET AL.	
	Examiner ROBERT HAVLIN	Art Unit 1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 June 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) 6-24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the claims: Claims 1-24 are currently pending.

Priority: This application is a 371 of PCT/JP04/19581 (12/27/2004), and claims foreign priority to JAPAN 2003-431686 (12/26/2003).

Election/Restrictions

Applicant previously elected Group I (claims 1-5). Applicant also elected the species of example 4 on page 64 of the specification pertaining to the synthesis of 4-((4S)-Hydroxy-(2S)-pyrrolidinylmethoxy)benzoic acid ethyl ester-1-carboxylic acid benzyl ester.

As detailed in the following rejections, the generic claim encompassing the elected species was not found patentable. Therefore, the provisional election of species is given effect, the examination is restricted to the elected species only, and claims not reading on the elected species are held withdrawn. Accordingly, claims 6-24 are hereby withdrawn.

Should applicant, in response to this rejection of the Markush-type claim, overcome the rejection through amendment, the amended Markush-type claim will be reexamined to the extent necessary to determine patentability of the Markush-type claim. See MPEP 803.02.

RESPONSE TO APPLICANT REMARKS

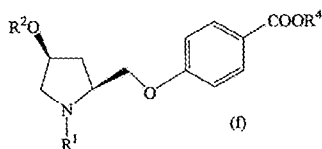
Claim Rejections - 35 USC § 103

1. Claims 1-5 were rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,707,987 ('987) in view of EP 0449191 A1 ('191) and March's Advanced Organic Chemistry, 5th ed., (2001) ("March").

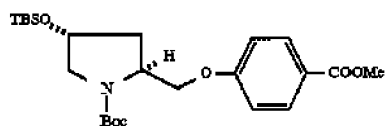
Applicant argues that the instant claims are distinguished from the teaching of the prior art because the instant claims are for the cis-form of hydroxyl-L-proline as the starting material. The examiner does not find this distinction to render the method non-obvious over the prior art because the method steps claimed would be substantially the same whether the starting material was either the cis or trans-form. Furthermore, one of ordinary skill in the art would recognize that the procedure taught in the prior art is equally applicable to both forms of hydroxyproline.

Applicant next argues that the compounds of Nakagawa and EP'191 are drawn to different classes of compounds from those of the instant claims. The examiner does not agree. The instant claims are for a compound of formula (f):

[F6]



and Nakagawa teaches the following compound:



which shares a substantial structural similarity. In addition, EP'191 is specifically referenced by Nakagawa as the method to make the starting material for the compound cited above. Thus, the prior art, and the combination thereof, is well within the contemplation of one of ordinary skill in the art.

Applicant also argues at the bottom of page 21 that there is no suggestion to use an acid starting material in place of an ester thereof. This argument is not persuasive because amino acids starting materials are commonly commercially available in ester form and are somewhat less reactive, therefore starting with the acid would be considered an equivalent as the ester from the perspective of one of ordinary skill in the art. In addition, the first step in the claims is to form the ester supporting the conclusion that one of ordinary skill in the art would consider the acid and ester interchangeable and select one over the other simply based on the readily available starting materials.

Next, applicant argues that the instant invention differs from the prior art because of the specific steps such as step 9 in Nakagawa which appears to invert the stereochemistry at the 4 position. Applicant also argues that one of ordinary skill in the art would be forced to employ a Mitsunobu reaction. These arguments are not persuasive as to the non-obviousness of the claims because the transformations referred to are outside of the scope of the instant claims; one of ordinary skill in the art would recognize the transformations taught by Nakagawa and EP'191 would equally be applicable to the cis-form of hydroxyproline and result in arriving at the invention as claimed.

Applicant next argues that the examiner mistakenly views the "Me" as a protecting group. The instant specification teaches R1 as a protecting group including alkyl:

... R.sup.1 represents a protecting group of the nitrogen atom (for the amino group).
Preferably, the protecting group is, for example, a group described in "Protective Groups in Organic Synthesis, edited by T. W. Greene and P. G. Wuts, John Wiley&Sons, Inc., New

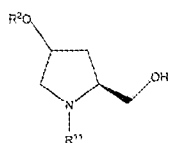
York, 1991." Specific examples of the protecting group include carbonate groups, acyl groups, alkyl groups, and aralkyl groups.

In addition, the Greene and Wuts reference cited teaches on page 23 (of the 3rd edition) that ethers are "the most used protective group in organic synthesis" and refers to the methyl ether as the simplest and most stable protecting group for a hydroxyl group. Thus, whether or not applicant characterizes the OMe group at position 4 as a protecting group, that is how it is acting in the reaction. This line of reasoning further buttresses the finding of obviousness because as applicant teaches in their own specification, protecting groups are interchangeable as taught by Greene and Wuts. Thus, one of ordinary skill in the art would certainly know to alter the protecting groups on Nakagawa and arrive at the claimed invention.

Therefore, the rejection of the claims is **maintained**.

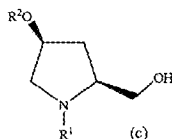
Double Patenting

2. Claims 1-5 were rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-5 of U.S. Patent No. 7345179. The claims are for a related method having similar reaction conditions that are arranged differently. Applicant argues that the starting compound of the '179 patent is not the same as the instant compound (c). The '179 starting material is:



(f)

wherein R^{11} represents a protective group of amino group, and R^2 represents hydrogen atom or a protective group of hydroxy group (with the proviso that when both R^{11} and R^2 are protective groups, they are not the same protective group) with an optionally substituted arylsulfonyl chloride or an optionally substituted alkylsulfonyl chloride in the presence of a base to produce a compound represented by formula (ff):



(c)

and (c) is:

. Thus applicant's argument is that

although the '179 patent teaches both cis and trans (stereochemistry is not specified at

the 4-position as shown above) starting materials for use in the same reaction steps, there would be no suggestion to use the cis-form. This argument is unpersuasive because the disclosure of '179 teaches that the method taught therein is applicable to both the cis and trans forms which would lead one of ordinary skill in the art to practice the instant invention. Accordingly, this rejection is **maintained**.

Claim Objections

The objection to claims 4 and 5 for being in an improper multiply dependent form is withdrawn.

Conclusion

The claims are not in condition for allowance. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ROBERT HAVLIN whose telephone number is

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(571)272-9066. The examiner can normally be reached on Mon. - Fri., 7:30am-5pm EST.

If attempts to reach the examiner by telephone are unsuccessful the examiner's supervisor, Joe McKane can be reached at (571) 272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Robert Havlin/
Art Unit 1626

/Rebecca L Anderson/
Primary Examiner, Art Unit 1626